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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,581	07/31/2003	Anne-Marie Rodriguez	0857/70669	5002
7590	10/20/2005			
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,581	Applicant(s) RODRIGUEZ ET AL.	
	Examiner Joanne Hama, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Application, filed July 31, 2003, claims priority to foreign applications 0209799, filed July 31, 2002, and 0302657, filed February 28, 2003, in France.

Claims 1-54 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-7, 9-12, 25-28, 48-54, drawn to adult non-transgenic multipotent human stem cells, classified in class 435, subclasses 455 and 366.
- II. Claims 2-12, 26-28, 49-54, drawn to adult multipotent human stem cells comprising at least one transgene, classified in class 435, subclass 366.
- III. Claims 13-24, drawn to a method for obtaining multipotent human stem cells comprising the following steps of:
 - culturing cells from a human tissue sample, in particular, human adipose tissue,
 - selecting two cell sub-populations termed a "CA" population and "CS" population, wherein the "CA" population has an adhesion rate of less than 12 hours, and the "CS" population has an adhesion rate of more than 12 hours,
 - enriching the "CA" population until a quiescent cell population is obtained, and
 - inducing proliferation of stem cells of the "CA" population,and the stems cells obtained by said method, classified in class 435, subclass 70.3.

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- IV. Claims 29-32, drawn to a use of adult multipotent human stem cells for in vivo tissue regeneration, classified in class 424, subclass 93.1.
- V. Claims 33-37, drawn to a method of making mesodermal cells, classified in class 435, subclass 377.
- VI. Claims 38-45, drawn to a screening method to identify agents that modulate differentiation of cells into cells of mesodermal lineage, classified in class 435, subclass 377.
- VII. Claims 46, 47, drawn to use of adult multipotent human stem cells in cosmetics and a cosmetic composition comprising a plurality of cells, classified in class 435, subclass 401.

The inventions are distinct, each from the other because of the following reasons:

Claim 1 link(s) inventions I and II. The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claim(s), claim 1.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

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requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II are patentably distinct. Invention I is drawn to adult non-transgenic multipotent human stem cells, while Invention II is drawn to adult transgenic multipotent human stem cells comprising at least one transgene. The cells of Inventions I and II are structurally different from each other. The searches for Inventions I and II are burdensome because the searches are not coextensive.

Inventions I/II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case while the multipotent human stem cells of Inventions I and II can be made by the method of Invention III, multipotent human stem cells can be obtained by other methods. For example, stromal cells can be isolated from bone marrow.

Inventions I/II and IV/V/VI/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cells of

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Inventions I and II can be used in many, different methods, as described in Inventions IV, V, VI and VII. Each method requires method steps that are distinct and different from other methods.

Inventions III and IV/V/VI/VII are patentably distinct. Invention III is drawn to a method of producing multipotent human stem cells, while Inventions IV/V/VI/VII are drawn to methods of using the multipotent human stem cells. While the multipotent stem cells is a common factor in these methods, each of the methods in each of these Inventions requires different method steps and results in products that are structurally different from each other.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claim 29 of Invention IV is generic for regeneration of tissue types: bone, adipose, muscle, or endothelial. One tissue type must be elected.

Claims 33 and 34 of Invention V are generic for a method of producing differentiated cells of the mesodermal lineage: adipocytes, osteoblasts, myocytes, or angiogenic. One cell of the mesodermal lineage must be selected.

Claim 38 of Invention VI is generic for a screening method that identify agents that modulate or inhibit differentiation of stem cells into the mesodermal lineage: adipocytes, osteoblasts, myocytes, and inhibition of differentiation. Either one type of mesodermal lineage or inhibition of differentiation must be selected. Further, should the adipocyte lineage be elected (claim 39), a further election of activity in adipocytes must

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be selected. These activities are drawn to lipolytic, anti-lipolytic, or insulin-sensitizing activity. One must be selected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29, 33, 34, 38, and 39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and the search for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

